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K013152

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS INFORMATION

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The ATAC PAK Direct HDL Reagent Kit, the ATAC Direct HDL Calibrator and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of HDL-cholesterol in serum and plasma. HDL-cholesterol results are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases, and for the assessment of the risk of developing cardiovascular disease.

The ATAC PAK Direct HDL Reagent determines HDL-cholesterol through the enzymatic action of cholesterol esterase and cholesterol oxidase after rendering the other sources of cholesterol inactive. The resulting increase in absorbance at approximately 600 nm is proportional to the HDL-cholesterol concentration in the sample.

The ATAC PAK Direct HDL Reagent Kit, calibrated with the ATAC Direct HDL Calibrator, is substantially equivalent to the Roche HDL-Cholesterol plus Reagent Kit, product no. 1930672, calibrated with Roche C.f.a.s HDL/LDL-C plus calibrator, product no. 1972235, which are currently marketed by Roche Inc. of Indianapolis, IN.

The effectiveness of ATAC PAK Direct HDL Reagent Kit and the ATAC Direct HDL used on the ATAC 8000 Random Access Chemistry System is shown by the following studies.

The recovery of HDL-cholesterol using the ATAC PAK Direct HDL Reagent is linear from 10 to 140 mg/dL as shown by the recovery of linearity standards that span the usable range. Linear regression statistics, with the regression line forced through the origin, compare standard recoveries to standard factors.

(ATAC Recoveries) = 0 mg/dL + 0.9570 x (Standard Factors), r = 0.995, sy.x = 4.5 mg/dL, n = 40

Precision is demonstrated by the replicate assay of commercially available control serum and a serum pool. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

Precision of HDL-Cholesterol Recoveries in mg/dL

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Serum 1	66	26	1.0	3.8%	1.9	7.4%
Serum 2	66	55	1.5	2.8%	2.8	5.1%
Serum 3	66	68	2.0	2.9%	2.7	3.9%

Mixed serum and plasma specimens, collected from adult patients, were assayed for HDL-cholesterol using the ATAC 8000 Random Access Chemistry System and another commercially available method. Results were compared by least squares regression and the following statistics were obtained.

Serum/Plasma Comparison
ATAC 8000 = 2.8 mg/dL + 0.912 x Competitive Reagent
r = 0.978 n = 156 range = 4.7 - 123 mg/dL

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Elan Diagnostics
is a division of Elan Pharmaceuticals

The detection limit claim of 10 mg/dL is documented through the repetitive assay of a diluted serum pool. The observed detection limit, calculated as two standard deviations of a 30 replicate within run precision study, is 1.5 mg/dL and is below the claimed limit.

The 30 day on board reagent stability and 14 day calibration stability claims are documented through the assay of serum controls over the claimed periods. In all cases, the total imprecision of HDL-cholesterol recoveries over the test periods are less than 3 mg/dL or 6%.

Wynn Stocking
Manager of Regulatory Affairs
Elan Diagnostics

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 0 9 2001

Mr. Wynn Stocking
Manager, Regulatory Affairs
Elan Diagnostics
1075 W. Lambert Road
Brea, CA 92821

Re: k013152
Trade/Device Name: ATAC PAK Direct HDL Reagent; ATAC Direct HDL Calibrator
Regulation Number: 21 CFR 862.1150; : 21 CFR 862.1475
Regulation Name: Calibrator; Lipoprotein test system
Regulatory Class: Class II; Class I, reserved
Product Code: JIS; LBS
Dated: September 19, 2001
Received: September 20, 2001

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 0 9 2001

510(k) Number (if known): K013152

Device Name: ATAC PAK Direct HDL Reagent and ATAC Direct HDL Calibrator

Indications For Use:

The ATAC PAK Direct HDL Reagent Kit, the ATAC Direct HDL Calibrator and the ATAC 8000 Random Access Chemistry System are intended for use as a system for the quantitative determination of HDL-cholesterol in serum and plasma. HDL-cholesterol results are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases, and for the assessment of the risk of developing cardiovascular disease.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

Respectfully,

Wynn Stocking

Wynn Stocking
Regulatory Affairs Manager
Elan Diagnostics

19 September, 2001

Russell Charles for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K013152

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)